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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/505,898 02/17/00 DAVE

K 065733/2262

EXAMINER

HM22/0913

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ART UNIT

PAPER NUMBER

1648

DATE MAILED:

09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/505,898

Applicant(s)

DAVE ET AL.

Examiner

Ulrike Winkler, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s): _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The Election/Restriction of 16 January 2001 is rendered moot in view of applicant's cancellation of claims 1-43 and insertion of new claim 44.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). Specifically, the citizenship was changed for Eva Emmerich.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 7, is attached to the instant office action.

Drawings

The drawings are objected to, please see Notice of Draftsperson's Review attached to the instant office action. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 44 step (a) is not clear because of ordinary skill in the art would not know what is meant by "an arthropod sample suspected of containing arthropods". There is no speculation required when starting with an arthropod containing sample. This could be clarified by amending the claim to read "obtaining a sample suspected of containing arthropods".

Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 44 step (b) it is not clear if it is enough just to separate the agent/parasite from the arthropod or if it will require additional treatment to expose the analyte (antigen) from the agent/parasite as well.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oprandy et al. (Journal of Clinical Microbiology, 1990, from applicant's IDS) in view of Huang et al. (U.S.Pat. No. 5,712,172).

The instant invention is drawn to a method of analyzing an arthropod sample for an agent that may cause disease in humans. The method contains the following steps: (a) obtaining the arthropod sample, (b) treating the sample to expose the analyte from the arthropod, (c) binding the analyte to form an analyte-reagent complex, and (d) detecting the analyte.

Oprandy et al. teach a dot-blot immunobinding assay to detect arthropod-borne agents. The method includes isolating the sporozoite from the mosquito, treating the sporozoite with a detergent to expose the antigen (see materials and methods). Alternately, sporozoite containing mosquitoes were homogenized together in the presence of detergent before spotting onto the filter. An antibody to detect the circumsporozoite protein was used to assay for the presence of the etiologic agent (see figure 2). The titration of the arthropod vector with SDS liberates antigen. The references also teaches that this same technique can be used for other arthropod – vectored etiologic agents (see page 1703, column 2, last paragraph). The reference does not teach applying the sample to a lateral flow device for the detection of the antigen.

Huang et al. teach the use of a lateral flow device for the detection of an anylyte in a single step. The lateral flow device contains a sample receiving region, an analyte detection

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region and an end region all made of porous material and capable of lateral flow. The anylyte detection region includes labeling reagents, a capture reagent and a control reagent. The device can be used for the detection of analytes directly from a biological sample. The reference does not teach detecting an etiologic agent from a mosquito sample.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the antibody detection reagents as taught by Oprandy et al. and apply them to the lateral flow device taught by Huang et al. which has the advantage of detecting an analyte from a biological sample in a single step. One having ordinary skill in the art would have been motivated to do this because in order to determine the risk of arthropod-vector disease spread it is necessary to survey the insect population for these etiologic agent. This information is important to assess the efficacy of insect control and abatement programs. One having ordinary skill in the art would have a high expectation of success in applying the antibodies and the methods of exposing the antigens using detergents as taught by Oprandy et al. and formulate them into the device as taught by Huang et al. The requirement as taught by Huang et al. is that the analyte must have at least one exposed epitope. Therefore, the instant invention is obvious over Oprandy et al. in view of Huang et al.

Conclusion

The claim is not allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pronovost et al. U.S. Pat. No. 5,686,315

Pawlak et al. U.S. Pat. NO. 5,766,961

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.



JEFFREY STUCKER
PRIMARY EXAMINER